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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,792	09/23/2003	Bernard E. Cabana	50150/064001	4322
21559	7590	03/29/2006	EXAMINER	
CLARK & ELBING LLP			SPIVACK, PHYLLIS G	
101 FEDERAL STREET			ART UNIT	
BOSTON, MA 02110			PAPER NUMBER	

1614

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,792

Applicant(s)

CABANA ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 6-29 and 40-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 30-39, 49-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Applicants' Reply to the Restriction Requirement filed January 20, 2006 is acknowledged. An election of Group II, claims 1-5, 30-39 and 49-51, was made without traverse.

Accordingly, claims 6-29 and 40-48 are withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. Re-affirmation of the election is requested when Applicants respond to this Office Action.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The abstract of the disclosure is objected to because the present Abstract is not directed to the subject matter presently under consideration. Correction is required.

See MPEP § 608.01(b).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 30-39 and 49-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-31 of copending Application No. 10/948608; over claims 21-23 of copending Application No. 11/020870; over claims 21-24 of copending Application No. 11/008597; over claims 22-31 of copending Application No. 10/948608; over claims 17, 36-45, 58 of copending Application No. 10/453155; over claims 47-61 of copending Application No. 10/318998; over claim 23 of copending Application No. 10/443351; and over claims 1-16 of copending Application No. 10/735344. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the co-pending applications recite the administration of rifalazil, or a rifamycin antibiotic, for the treatment of an atherosclerosis-associated disease, such as coronary artery disease.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claims 30-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and under 35 U.S.C. 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, Applicant must convey with

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reasonable clarity, as of the filing date, that Applicant was in possession of the claimed invention. The issue of a lack of adequate written description also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996), (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that Applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. For example, a specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claims and determined that the invention would work for its intended purpose. An Applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Applicant was in possession

of the claimed invention as a whole.

An Applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics that provide evidence that Applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Applicants have not conveyed possession of the invention with reasonable clarity to one skilled in the art. There are no working examples directed to administration of rifalazil to treat or prevent the development of an atherosclerosis-associated disease in a patient. Further, the metes and bounds of "preventing the development of an atherosclerosis-associated disease" cannot be precisely determined. In view of the various etiologic factors and risk factors involved in the development of atherosclerosis-associated diseases, the skilled artisan would reasonably require a more detailed description of the therapy contemplated. Applicants have not provided any working examples that would describe to one of ordinary skill in the art an embodiment that meets all the limitations thereof. Applicants urge a possible link between bacterial infections and a broad set of inflammatory, autoimmune and immune deficiency diseases. A quantum leap is then made to a method for preventing the development of atherosclerosis-associated diseases. Applicants have not described with sufficient clarity that the administration of rifalazil will treat or prevent such diseases. Sufficient guidance to support predictable operability of the invention to one of ordinary skill in the art is absent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 30-39 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sayada, C.B., US 2003/0236265.

Sayada teaches the oral administration of rifalazil to treat the atherosclerosis-associated disease, coronary artery disease. Multiple drug therapy for the treatment of atherosclerosis, as required by claims 31-37, comprising administering anti-inflammatory agents, platelet aggregation inhibitors, anticoagulants, antipyretic or lipid-lowering agent is well established. See page 8, claims 23, 26 and 27, as well as page 2, paragraph [0024], where optimal dosages are disclosed. The mere placement of instructions within a formulation comprising rifalazil would have been within the general knowledge of one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so to promote proper use of the formulation to patients in need thereof and to facilitate patient compliance with a prescribed regimen. Providing such a formulation in a portable container, or in unit dose packaging, that can be transported to allow for convenient dosing is conventional. It has been held that Applicant is not entitled to patent a known product by simply attaching a set of instructions to that product. See *In re Ngai*, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). The determination of an optimal dosing regimen is well within the purview of those skilled in the art through no more than routine experimentation.


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 18, 2006


Phyllis Spivack
1614 **PHYLLIS SPIVACK**
PRIMARY EXAMINER